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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,355

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Robert K. Gieseler

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EXAMINER

HILL, KEVIN KAI

ART UNIT

PAPER NUMBER

1633

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,355	<b>Applicant(s)</b> GIESELER ET AL.
	<b>Examiner</b> KEVIN HILL	<b>Art Unit</b> 1633

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9,13,15,16,20-24,26-28,37,50,52,53,55-59,75-79 and 81 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,13,20-24,55 and 75-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,9,15,16,26-28,37,50,52,53,56-59 and 81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
|---|---|

### **Detailed Action**

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28, 2011 has been entered.

#### ***Amendments***

Applicant's response and amendments, filed April 28, 2011 and May 16, 2011, to the prior Office Action is acknowledged. Applicant has cancelled Claims 3-5, 10-12, 14, 17-19, 25, 29-36, 38-49, 51, 54, 60-74 and 80, withdrawn Claims 7-8, 13, 20-24, 55 and 75-79, and amended Claims 1 and 81.

Claims 7-8, 13, 20-24, 55 and 75-79 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on November 13, 2009. Applicant is reminded that the restriction/election requirement was made final in the Office Action of February 18, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP §821.01.

Claims 1-2, 6, 9, 15-16, 26-28, 37, 50, 52-53, 56-59 and 81 are under consideration.

If the claims are amended, added and/or canceled in response to this Office Action, then Applicant is required to follow Amendment Practice under 37 C.F.R. §1.121 AND A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.

#### ***Examiner's Note***

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the May 16, 2011 response will be addressed to the extent that they apply to current rejection(s).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

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1. **Claim 50 is rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is dependent upon cancelled Claim 10. In light of Applicant's amendments to the claims, the Examiner interprets Claim 50 to be dependent upon Claim 1.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

2. **The prior rejection of Claims 1-2, 6, 9, 15-16, 26-28, 37 and 81 under 35 U.S.C. 103(a)** as being unpatentable over Hartmann et al in view of Arigita et al (2003) and Figdor et al **is withdrawn** in light of Applicant's amendment to the claims, moving a limitation of prior dependent Claim 10 into independent Claims 1 and 81.

3. **Claims 1-2, 6, 9, 15-16, 26-28, 37, 52 and 81 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Hartmann et al in view of Arigita et al, Figdor et al and LaGrone.

The limitations of instant Claims 1-2, 6, 9, 15-16, 26-28, 37, 52 and 81 were recited in prior Claims 1-2, 6, 9-10, 15-16, 26-28, 37, 52 and 81 and previously rejected. The disclosure of Hartmann et al, Arigita et al, Figdor et al and LaGrone are provided in prior Office Actions and will not be iterated herein.

***Response to Arguments***

Applicant iterates arguments from a prior Response to Amendment (May 18, 2010).

The Examiner's response to Applicant's iterated arguments are discussed in a prior Office Action. The Examiner's response to new arguments will be discussed below.

Applicant argues that it should be noted regarding the patentability of the present invention that it is not relevant whether it was known that particular agents such as lectins inhibit HIV and/or other viruses, but instead the inventive idea of the present inventors to use active compounds, e.g. lectins, not as freely soluble agents, but as (a) encapsulated and (b) targeted compounds.

Applicant's argument(s) has been fully considered, and so noted.

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Applicant argues that to further differentiate the present invention from the prior art the active agent has been limited to be a plant lectin, an antiviral drug, an anti-HIV drug, an anti-cancer drug, a cytotoxic agent, an apoptosis inhibitor, an antifungal drug, an antibacterial drug, or an immunomodulatory agent.

Applicant's argument(s) has been fully considered, but is not persuasive. As discussed in a prior Office Action, at the time of the invention, LaGrone disclosed a method of delivering an active agent to a reservoir cell, i.e. HIV- infected reservoir cells, specifically mononuclear phagocytic lineage cells that eventually become dendritic cells (col. 4, lines 25-37, 52-58), comprising the administration of a plant lectin (col. 4, lines 8-24) encapsulated within a liposome (col. 10, line 9). Thus, Applicant's amendment to further limit the instantly claimed invention does not further differentiate the present invention from the prior art.

Applicants question whether a person skilled in the art would "substitute a first active agent as taught by Hartmann et al. and/or Arigita et al with a second active agent according to LaGrone with a reasonable expectation of success because the simple substitution of one known argument for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. A person skilled in the art would never have done this without having an incentive. In the medical area these substitutions are never "simple" contrary to what is stated by the Office. Clearly the Office is using impermissible hindsight. Applicants insist that the solutions of Hartmann and Arigita and/or LaGrone are totally different from each other, and as such, not combinable.

Applicant's argument(s) has been fully considered, but is not persuasive.

As a first matter, it is noted that Applicant did not traverse this issue in the reply filed May 18, 2010 after the first Office Action mailed February 18, 2010.

As a second matter, liposomes have long been recognized in the art as pharmaceutically acceptable delivery vehicle for a multitude of therapeutic agents. To put it another way, it is routine practice in the art to substitute a first therapeutic agent for a second therapeutic agent.

As a third matter, as discussed in a prior Office Action, an artisan would be motivated [incentive] to substitute a first active agent with a second active agent, specifically a plant lectin because LaGrone suggests that the use of plant lectins to selectively destroy HIV-infected

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reservoir cells to facilitate the eradication of HIV or severely curtail the progress of HIV infection in a patient in need of treatment.

As a fourth matter, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the Examiner reached a conclusion of obviousness based upon the knowledge which was within the level of ordinary skill at the time the claimed invention was made. Thus it is the Examiner's position that the ordinary artisan would have a reasonable expectation of success because the simple substitution of one known active agent for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention

4. **Claims 58-59 stand rejected under 35 U.S.C. 103(a)** as being unpatentable over Hartmann et al in view of Arigita et al (2003), Figdor et al and LaGrone, as applied to Claims 1-2, 6, 9, 15-16, 26-28, 37, 52 and 81 above, and in view of Haas et al.

5. **Claims 50 and 53 stand rejected under 35 U.S.C. 103(a)** as being unpatentable over Hartmann et al in view of Arigita et al (2003), Figdor et al, LaGrone and Haas et al, as applied to Claims 1-2, 6, 9, 15-16, 26-28, 37, 52, 58-59 and 81 above, and in view of Charan et al (2000).

6. **Claim 57 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Hartmann et al in view of Arigita et al (2003), Figdor et al, LaGrone, Haas et al and Charan et al (2000), as applied to Claims 1-2, 6, 9, 15-16, 26-28, 37, 50, 52, 58-59 and 81 above, and in view of Matthiesen.

7. **Claim 56 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Hartmann et al in view of Arigita et al (2003), Figdor et al, LaGrone, Haas et al and Charan et al (2000) and Matthiesen, as applied to Claims 1-2, 6, 9, 15-16, 26-28, 37, 50, 52, 57-59 and 81 above, and in view of Khwaja.

### ***Conclusion***

8. No claims are allowed.

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All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP §706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-5:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/

Examiner, Art Unit 1633